510(K) SUMMARY

JAN 11 2008

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K073198

1. Submitter's Identification:

Microlife Intellectual Property GmbH, Switzerland

Espenstrasse 139
9443 Widnau / Switzerland

Date Summary Prepared: October 30, 2007

2. Name of the Device:

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Home (BP3MX1-1).

3. Information for the 510(k) Cleared Device (Predicate Device):

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3AC1-1 PC, K#060686.

4. Device Description:

Microlife Upper Arm Automatic Blood Pressure Monitor, Model WatchBP Home is designed to measure the systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the Upper arm. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronic capacitive pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well - known technique in the market called the "oscillometric method".
The device has <DIAG> and <USUAL> measurement mode. In additional, the device can be used in connection with your personal computer **(PC)** running the WatchBP 1.0 software. The memory data can be transferred to the PC by connecting the monitor via cable with the PC.

5. Intended Use:

The Microlife upper arm Blood Pressure Monitor, Model WatchBP Home (BP3MX1-1) is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm.

The device can be used in connection with your personal computer **(PC)** running the WatchBP 1.0 software. The memory data can be transferred to the PC by connecting the monitor via cable with the PC.

6. Comparison to the 510(k) Cleared Device (Predicate Device):

Both devices use the well-known oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and pulse rate. An upper arm cuff is inflated automatically; deflate rate is controlled but a factory set bleed valve and the deflation pressures are transferred via tubing to a sensor in both units. Moreover both devices can be used in connection with PC. The memory data can be transferred to the PC by connection the monitor via cable with the PC.

The differences between the subject WatchBP Home (BP3MX1-1) and the predicate device (BP3AC1-1 PC) are as follows:

1. **Irregular heartbeat detection function:**

The predicate device, BP3AC1-1 PC, has the irregular heartbeat detection function, while the subject device, the WatchBP Home (BP3MX1-1) does not have this function.

2. **Measurement mode:**

BP3AC1-1PC contains a switchable average mode in which the device automatically repeats 3 individual measurements cycles, each with a rest time of 15 seconds in between. After that the average of these 3 individual measurements is calculated and shown on the display. By certain key operation the user can access the individual results of the measurements.

WatchBP Home contains a switchable <DIAG> and <USUAL> mode.

In <DIAG> mode , the device allows for only two blood pressure measurements to be taken in the morning (6-9am) and another two in the evening (6-9pm), each with a rest time of 60 seconds in between. After completing seven days, the device displays a symbol suggesting that the patient should consult his/her doctor. Pressing the memory button on the device displays the average of all measurements after discarding those of the first day.

In <USUAL> mode, the device functions like a normal blood pressure monitor – single measurements are automatically stored up to 250 measurements and can

be evaluated by a doctor.

3. Blood Pressure Analyzer Software:

The two devices can be used in connection with your personal computer (PC) running the Microlife Blood Pressure Analyzer software. The memory data can be transferred to the PC by connecting the blood pressure monitor to personal computer via USB cable. All the memory data can be transferred to the connected computer through USB cable and be shown on the computer monitor. After transferred to computer, the memory data can then be saved in the personal computer memory. Different software is employed for the predicate and subject devices.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information demonstrating safety and effectiveness of the Microlife Automatic Blood Pressure Monitor, Model WatchBP Home in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance Requirements.

The following testing was conducted to support this subject submission:

a. Reliability Test - Storage test
b. Reliability Test - Operating test
c. Reliability Test - Vibration test
d. Reliability Test - Drop test
e. Reliability Test - Life test
f. EMC Test
g. PC-link software WatchBP 1.0 test report

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that the Microlife Upper Arm Automatic Blood Pressure Monitor, Model WatchBP Home tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

ANSI/AAMI SP10-2002 "National Standard for Manual, Electronic or Automated Sphygmomanometers" testing was performed. All relevant sections were addressed and testing conducted. The WatchBP Home met all relevant requirements of this standard, as applicable to our modified device.

The WatchBP Home is, from a technical point of view, identical to the predicate device, Model BP3BT0-A. Moreover, the measurement algorithm and its program

codes of the WatchBP Home remain unchanged. The fundamental scientific technology of the modified WatchBP Home device is the same as the predicate BP3BT0-A device.Therefore the performance of the WatchBP Home in terms of blood pressure measurement would be identical with performance of the predicate BP3BT0-A device. Repeat clinical testing in accordance with AAMI Standard SP-10 for the subject WatchBP Home device is therefore not necessary as clinical testing results were not affected by the changes to the subject modified device.

9. Software information:

Software validation was conducted in accordance with a moderate level of concern designation in accordance with the FDA November 2005 document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". In addition, since the subject device requires the use of an off-the-shelf software to operate the PC-link function, we adhered to the September 1999 FDA document, "Guidance for Off-the-Shelf Software Use in Medical Devices".

10. Conclusions:

We have demonstrated that there are no significant differences between the subject device, the Microlife Automatic Blood Pressure Monitor, Model WatchBP Home and the predicate Model BP3AC1-1 PC in terms of safety and effectiveness based on electrical, mechanical and environmental test results, and the ANSI/AAMI Voluntary Standard, SP10-2002 test results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 11 2008

Microlife Intellectual Property GmbH
c/o Ms. Susan Goldstein-Falk
Official Correspondent
MDI Consultants, Inc.
55 Northern Blvd, Suite 200
Great Neck, NY 11021

Re: K073198
Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBPHome (BP3MX1-1)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: November 9, 2007
Received: November 13, 2007

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit#B

Indications for Use

510(k) Number (if known): K073198

Device Name: Microlife Upper Arm Automatic Blood Pressure Monitor, Model WatchBP Home (BP3MX1-1)

Indications For Use:

The Microlife Upper Arm Blood Pressure Monitor, Model WatchBP Home (BP3MX1-1) is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm.

The device can be used in connection with your personal computer **(PC)** running the WatchBP 1.0 software. The memory data can be transferred to the PC by connecting the monitor via cable with the PC

Prescription Use _____ **AND/OR** **Over-The-Counter Use** __X_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K073198